

November 9, 2001

Dr. Bill Stokes, Director
NTP Interagency Center for the Evaluation of Alternative
Toxicological Methods (MD EC-17)
National Institute of Environmental Health Sciences
P.O. Box 12233
Research Triangle Park, NC 27709

SUBMITTED ELECTRONICALLY TO: niceatm@niehs.nih.gov

Dear Dr. Stokes:

We are pleased to submit comments in response to the National Institute of Environmental Health Sciences' (NIEHS) *Federal Register* notice dated September 28, 2001, inviting public comment on the background review document entitled "EPISKIN™, EpiDerm™ and Rat Skin Transcutaneous Electrical Resistance (TER) Methods: *In Vitro* Test Methods for Assessing the Dermal Corrosivity Potential of Chemicals," and recommendations from the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) on the use of these methods. These comments are submitted on behalf of People for the Ethical Treatment of Animals (PETA) and our over 750,000 members who are concerned about the continued use of animals in cruel and non-validated corrosivity tests.

We have reviewed the formal validation studies of the EPISKIN™, EpiDerm™ and Rat Skin TER assays that have been conducted under the auspices of the European Center for the Validation of Alternative Methods (ECVAM), and concur that these methods have been amply demonstrated to be scientifically valid for the assessment of corrosivity in all classes of chemicals. We also call your attention to the fact that an expert panel of the Organization for Economic Cooperation and Development (OECD) recently reviewed these methods and endorsed their acceptance. We therefore urge the immediate acceptance of these ECVAM-validated and expert-endorsed *in vitro* assays by both ICCVAM and regulatory authorities throughout the United States.

However, we strongly object to ICCVAM's recommendation that these methods be used in the context of a "weight-of-evidence approach in an integrated testing scheme," whereby "negative *in vitro* corrosivity responses shall be followed by *in vivo* dermal corrosion/irritation testing." Once a test method has achieved validation, its results should, by definition, be accepted as reliable and relevant without question or the demand for additional "confirmatory" studies. It is therefore inappropriate for ICCVAM to issue a recommendation that clearly second guesses the reliability and/or relevance of test methods that it has just acknowledged to be validated. It is doubly inappropriate for ICCVAM to suggest that the results of a non-validated test method (i.e., the current *in vivo* assay) could possibly provide a superior prediction of a chemical's hazard to humans over those of a fully validated test method.



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Therefore, we urge ICCVAM to amend its recommendations to accept the use of any and all of the currently available and validated *in vitro* corrosivity assays (i.e., EPISKIN™, EpiDerm™, the Rat Skin TER assay) as stand-alone tests for the purposes of hazard identification and risk assessment.

Thank you for your attention to these comments.

Sincerely,

A handwritten signature in black ink, appearing to read 'T. Seidle', with a stylized flourish at the end.

Troy Seidle, B.Sc.
Research Associate
Research & Investigations Department